1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qivitan 25 mg/ml suspension for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Cefquinome 25 mg
(equivalent to 29.64 mg cefquinome sulfate)

Excipient:

Qualitative composition of excipients and other constituents
Ethyl oleate

White to slightly yellowish suspension

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

For the treatment of bacterial infections in cattle and pigs caused by the Gram positive and Gram negative microorganisms sensitive to cefquinome.

Cattle:
Respiratory disease caused by *Pasteurella multocida* and *Mannheimia haemolytica.*
Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot).
Acute *E.coli* mastitis with signs of systemic involvement.

Calves:
E.coli septicaemia in calves.

Pigs:
For the treatment of bacterial infections of the lungs and respiratory tract caused by *Pasteurella multocida, Haemophilus parasuis, Actinobacillus pleuropneumoniae, Streptococcus suis* and other cefquinome-sensitive organisms.

Mastitis-Metritis-Agalactia syndrome (MMA) with involvement of *E.coli, Staphylococcus* spp., *Streptococcus* spp. and other cefquinome sensitive organisms.

Piglets:
Reduction of mortality in cases of meningitis caused by *Streptococcus suis*.
For the treatment of:
Arthritis caused by *Streptococcus* spp., *E. coli* and other cefquinome-sensitive organisms.
Epidermitis (mild or moderate lesions) caused by *Staphylococcus hyicus.*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, ß-lactam antibiotics, or to any of the excipients.

Do not use in animals less than 1.25 kg body weight.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In case of occurrence of allergic reaction, the treatment should be withdrawn.

The use of cefquinome should be restricted to appropriate use according to the labelled indications in the target animal species.

The veterinary medicinal product selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) which may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, the veterinary medicinal product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis), to first line treatment.

Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from the instructions given in the SPC, may increase the prevalence of such resistance. Whenever possible, the product should only be used based on susceptibility testing.
Inappropriate use of the product may increase the prevalence of bacteria resistant to cefquinome and may decrease the effectiveness of treatment with other beta lactam antibiotics, due to the potential for cross resistance.
The veterinary medicinal product is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programs. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- Cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
- People with known hypersensitivity to cefquinome sulfate should avoid contact with the veterinary medicinal product.
- Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
- If you develop symptoms following exposure such as a skin rash, seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.
- Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle and pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction
Undetermined frequency (cannot be estimated from the available data):	Injection site reaction, Injection site lesion[1]

[1] Lesions are repaired 15 days after last administration.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Laboratory studies in rat and rabbit have not produced any evidence of teratogenic, embryotoxic or maternotoxic effects. The safety of the veterinary medicinal product has not been established in cow and sow during pregnancy.

Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Due to an undesirable pharmacodynamic interaction, do not use cefquinome simultaneously with pharmaceuticals acting bacteriostatically.

3.9 Administration routes and dosage

Intramuscular use.

Species	**Indication**	**Dosage**	**Frequency**
Cattle	Respiratory disease caused by *Pasteurella multocida* and *M. haemolytica* Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 3 to 5 consecutive days.
	Acute *E. coli* mastitis with signs of systemic involvement	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 2 consecutive days.
Calves	*E. coli* septicaemia	2 mg cefquinome/kg bw (4 ml/50 kg bw)	Once daily for 3 to 5 consecutive days.
Pigs	Respiratory disease	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 3 consecutive days.
	MMA	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 2 consecutive days.
Piglets	Meningitis Arthritis Epidermitis	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 5 consecutive days.

Studies have indicated the advisability of giving second and subsequent injections at different injection sites. The preferred injection site is in the muscular tissue of the mid neck.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Shake the vial well before using.

The veterinary medicinal product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry sterile needle and syringe. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes, for example when treating piglets. When treating groups of animals, use a draw-off needle.

The rubber stopper of the vial may be safely punctured up to 50 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdoses of 20 mg/kg/day in cattle and 10 mg/kg/day in pigs and piglets have been well tolerated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Cattle: Meat and offal: 5 days.
Milk: 24 hours.
Pigs: Meat and offal: 3 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01DE90

4.2 Pharmacodynamics

The antibacterial drug cefquinome is a broad-spectrum cephalosporin of the fourth-generation which acts by inhibition of the cell wall synthesis. It is bactericidal and is characterised by its broad therapeutic spectrum of activity and a high stability against penicillinases and beta-lactamases.

In vitro activity has been demonstrated against common Gram positive and Gram negative bacteria including bovine strains of *Pasteurella multocida, Mannheimia haemolytica, Escherichia coli* and anaerobes (*Bacteroides* spp., *Fusobacterium* spp.) and against porcine strains of *Streptococcus* spp., *Staphylococcus* spp., *Pasteurella multocida, Haemophilus parasuis, Actinobacillus pleuropneumoniae* and *Escherichia coli.*

According to susceptibility data from European countries on bacteria isolated in the period 2004 to 2011, bovine strains of *Pasteurella multocida, Mannheimia haemolytica* and non-enteric *Escherichia coli* as well as porcine strains of *Pasteurella multocida, Actinobacillus pleuropneumoniae, Haemophilus parasuis, Streptococcus suis* and *Escherichia coli* were found to be highly susceptible to cefquinome (MIC90 $\leq$ 0.25 µg/ml). Porcine strains of *β-haemolytic Streptococci* (MIC90 = 1 µg/ml), *Staphylococcus hyicus* (MIC90 = 1 µg/ml) and *Staphylococcus aureus* (MIC90 = 4 µg/ml) *showed* moderate susceptibility.
Cefquinome as a fourth generation cephalosporin combines high cellular penetration and ß-lactamase stability. In contrast to cephalosporins of previous generations, cefquinome is not hydrolysed by chromosomally–encoded cephalosporinases of the Amp-C type or by plasmid mediated

cephalosporinases of some enterobacterial species. However, some extended spectrum beta-lactamases (ESBL) can hydrolyse cefquinome and cephalosporins of other generations. The potential for resistance development against cefquinome is rather low.

High-level resistance to cefquinome would require the coincidence of two genetic modifications, i.e. hyperproduction of specific ß-lactamases as well as decreased membrane permeability.

4.3 Pharmacokinetics

In cattle peak serum concentrations of about 2 µg/ml are reached within 1.5-2 hours after intramuscular administration at the dose of 1 mg/kg. Cefquinome has a relatively short terminal half-life (2.5 hours), is < 5 % protein bound and excreted unchanged in the urine. In pigs or piglets, at 2 mg/kg dosage, maximum serum concentrations of around 5 µg/ml are measured within 15 to 60 minutes after intramuscular injection. The average half-life of Cefquinome in piglets is approximately 1.6 – 2.5 hours after intramuscular injection.

Cefquinome binds poorly to plasma proteins and therefore penetrates into the cerebrospinal fluid (CSF) and the synovial fluid in pigs. The concentration profile is similar between the synovial fluid and the plasma. The concentrations reached in the CSF 12 hours after treatment are similar to those in plasma.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening of the immediate packaging: 28 days

5.3 Special precautions for storage

Protect from light.

5.4 Nature and composition of immediate packaging

50 ml, 100 ml and 250 ml colourless Type II glass vials with a grey chlorobutyl rubber stopper, fluoro polymer coated and sealed with an aluminium cap in a cardboard box.

Pack sizes:
1 x 50 ml, 6 x 50 ml or 12 x 50 ml
1 x 100 ml, 6 x 100 ml or 12 x 100 ml
1 x 250 ml, 6 x 250 ml or 12 x 250 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LIVISTO Int'l, S.L.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10425/003/001

8. DATE OF FIRST AUTHORISATION

27/01/2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

19/06/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).